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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,307	01/07/2002	Stephen Kent	229752001400	2826

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,307

Applicant(s)

KENT, S., ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 09/831,307
Applicants: Kent, S., et al.

Docket No.: 229752001400
Filing Date: 01/07/02

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 13 September, 2006. Claims 1 and 17-19 are pending in the instant application.

37 C.F.R. § 1.75(c)

The previous objection to claim 38 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is moot in view of applicants' amendment.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and

invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1 and 17-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Paoletti et al. (1998) in view of Ramshaw et al. (1999). The claims are directed toward a fowlpox virus vector encoding a heterologous antigen (e.g., HIV Gag and/or Pol) and cytokine (e.g., γ -IFN) and methods of using said vector to induce a viral-specific immune response. As previously set forth, Paoletti and colleagues provide **fowlpox** viral vectors (e.g., **TROVAC**) encoding lentiviral (e.g., HIV, SIV) gene products (e.g., **Gag**, Pol, Env) that are suitable for inducing viral-specific immune responses (see col. 5, lines 19-36; col. 7, lines 1-20; cols. 153-154). This teaching does not disclose the utilization a second nucleic acid encoding a cytokine that functions as an adjuvant.

Ramshaw and colleagues provide recombinant viral vectors (e.g., **poxviruses**) carrying a first nucleic acid encoding a viral immunogen (e.g., HIV-1) and a second nucleic acid encoding a cytokine adjuvant (e.g., IL-2, γ -IFN) that facilitates the immune response to the immunogen (see abstract; col. 2, lines 6-41; col. 3, lines 34-55; col. 4, lines 27-34 and 44-58; col. 5, lines 5-33 and 60-65). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the fowlpox expression vector of Paoletti et al. (1998), to include a second nucleic acid encoding a cytokine adjuvant as taught by Ramshaw et al. (1999), since this would reasonably be expected to enhance the immune response to the HIV-1 antigen of interest. Both the motivation and a reasonable expectation of success were clearly present in the prior art.

Response to Arguments

Applicants traverse and again submit that there is no motivation to combine the references to arrive at the claimed invention. This position is clearly untenable in view of the prior art. As previously set forth, there is no question that Ramshaw et al. (1999) teach that the inclusion of a nucleotide sequence encoding a **cytokine** (e.g., IL-2, γ -IFN), as well as, a nucleotide sequence encoding a **heterologous antigen** (e.g., HA), in the genetic background of a poxvirus (e.g., vaccinia virus) results in strong immune response against the heterologous antigen. The authors unambiguously state (see col. 2, lines 22-36) that "the co-expression of the lymphokine with the antigenic polypeptide(s) ensures that on administration of the vaccine the lymphokine and antigenic polypeptide(s) are delivered together at the same time and at the same site, giving an improved immune response to the antigenic polypeptide(s)." The only limitation of this teaching is that it does not disclose a fowlpox virus construct or a heterologous HIV antigen. However, the inventors state that the antigenic polypeptide may be "derived from the human immunodeficiency virus (HIV), together with a second nucleotide sequence capable of being expressed as all or an active part a lymphokine effective at enhancing or modifying the immune response of the individual to the HIV antigenic polypeptide" (col. 3, lines 43-50) and that other poxvirus vaccine vectors may be employed (col. 5, lines 60-65). Paoletti and colleagues provide fowlpox viral vectors (e.g., TROVAC) encoding lentiviral (e.g., HIV, SIV) gene products (e.g., Gag, Pol, Env) that are suitable for inducing viral-specific immune responses (e.g., see Example 3). Thus, contrary to applicants' assertions, there would have been more than sufficient motivation to modify the compositions of Paoletti et al. (1998), to include a second nucleic acid encoding a cytokine

adjuvant as taught by Ramshaw et al. (1999), since this would reasonably be expected to enhance the immune response to the HIV-1 antigen of interest. Contrary to applicants' assertion, both the motivation and a reasonable expectation of success were clearly present in the prior art. Moreover, applicants have failed to proffer any evidence that would teach away from the claimed invention.

Applicants again suggest that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning. Applicants are reminded that it must be recognized that any judgement on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. *In re McLaughlin*, 443 F.2d 1392; 170 U.S.P.Q. 209 (C.C.P.A. 1971). As set forth *supra*, there was clearly sufficient motivation to include a second gene encoding a cytokine, such as γ -IFN, in a fowlpox recombinant vaccine vector since it was clearly emphasized that this would lead to the development of strong immune response against the immunogen of interest. All of applicants' arguments have been carefully considered but are not deemed to be persuasive.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 24, 25, 30, and 31 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is moot in view of applicants' amendment.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-

8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

26 November, 2006